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August 28, 2000

Dockets Management Branch HFA-305 Food and Drug Administration 5630 Fishers Lane, room 1061 Rockville, MD 20852

Docket #00N-1380: Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair

Dear Madam/Sir:

This is a request to extend the deadline for submission of comments for the above-referenced docket number (00N-1380: Human Bone Allograft) for an additional sixty days to a new deadline of November 1, 2000.

The comment submission deadline of September 1 does not provide sufficient time to respond to information presented at the August 2 public meeting (transcript just became available on August 24, 2000) and to the questions and background information provided in the July 18, 2000 Federal Register Notice announcing the August 2 public meeting.

AdvaMed appreciates your consideration of this request.

Sincerely,

Janet Trunzo

Associate Vice-President

Technology and Regulatory Affairs

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